

## REMARKS

### Status of the claims

Claims 59-130 are pending.

Claims 59 - 109, 118, 119, and 127 - 130 have been withdrawn from consideration.

Claims 110 - 117 and 120 - 126 stand rejected, and claims 59 - 130 are subject to restriction and/or election requirement.

Applicants herein cancel claims 59 - 109 to non-elected restriction groups without prejudice to applicants' prosecuting these claims or claims of similar scope in one or more continuation or divisional applications.

### Priority

According to the Examiner, priority document, US 60/207,456, filed on May 26, 2000, has been marked lost by the US Patent and Trademark Office ("PTO").<sup>1</sup> Pursuant to the Examiner's request, applicants provide herewith a copy of the Filing Receipt for priority document US 60/207,456, documenting the filing of this application in the PTO on May 26, 2000. Applicants also provide, as a courtesy to the Examiner, an electronic copy of US 60/207,456, as filed, on CD-R, which would otherwise occupy over 1200 pages of printed text.

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<sup>1</sup> Applicants note that this document is also a priority document for several PCT International Applications and is one of several such documents that have recently been transmitted to the International Bureau of WIPO. It is therefore possible that the missing document is currently in the PCT Division of the PTO.

The Examiner notes that in order to obtain priority under 35 U.S.C. 119(e) or 120 based upon a previously filed application, specific reference to the earlier filed application must be made in the instant application. The Examiner further notes that for the benefit of priority under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This information should appear as the first sentence of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet.

Applicants respectfully submit that claims for priority were properly included in the instant application, as filed.

The first sentence of the application recited a complete list of the priority documents. In addition, the Declaration (see enclosed copy), filed as part of the instant application on May 23, 2001, provided the status of the prior U.S. applications and the prior PCT applications designating the U.S. to which priority was claimed. Finally, the Application Data Sheet (see enclosed copy), filed as part of the instant application on May 23, 2001, contained the above information, as well as the relationships between the instant application and the prior-filed copending nonprovisional applications and international applications designating the United States.

All of the necessary information was thus submitted during the pendency of the application and within the later of four months from the actual filing date of the application or

sixteen months from the filing date of the prior application as required by 37 C.F.R. § 1.78(a)(2)(ii) and (a)(5)(ii) for a utility application filed under 35 U.S.C. 111(a) on or after November 29, 2000.

However, in order to simplify the entry of the benefit claims into the PTO's computer database, applicants have amended the first sentence of the specification to include all of the information contained in the Declaration and Application Data Sheet as filed in a form compliant with the PTO's notice dated 26 February 2003 ("Claiming the Benefit of a Prior-Filed Application under 35 U.S.C. §§ 119(e), 120, 121, and 365(c)").

#### IDS

The Examiner indicates that the instant application file lacks the documents listed on the Information Disclosure Statements, paper no. 5, entered December 3, 2001, paper no. 7, entered August 23, 2002, and paper no. 9, entered October 4, 2002. Applicants enclose herewith copies of acknowledgement postcards, date-stamped by the PTO November 30, 2001, August 23, 2002, and October 4, 2002, respectively, indicating that copies of the listed documents were indeed received by the PTO for the instant application. As a courtesy, Applicants will hand-deliver replacement copies of these documents to the Examiner. Applicants respectfully request that the Examiner acknowledge consideration of the cited references prior to allowance of any claims by return of initialed copies of the accompanying Form PTO-1449s.

### OBJECTIONS

The Examiner objects to the presence of an embedded hyperlink and/or other form of browser-executable code in the disclosure. References to hyperlinks in the specification have been amended to provide instead a description of the organization hosting the relevant web sites.

The Examiner objects that the title of the invention is not descriptive. The title has been amended to make it descriptive of the invention as presently claimed.

### REJECTIONS

#### 35 U.S.C. § 112, ¶ 2

The Examiner has rejected claims 110-117 and 120-126 under 35 U.S.C. § 112, ¶ 2 for being vague and indefinite with respect to the term "desired". Applicants have amended claim 110 to remove this term and respectfully request that this rejection be withdraw.

The Examiner has rejected claim 125 and its dependent claim 126 under 35 U.S.C. § 112, ¶ 2 for being vague and indefinite with respect to the phrase "the complements thereof". Applicants submit that the amendment of claim 125 to read "the complete complements thereof" overcomes this rejection and respectfully request that the claim rejection be withdrawn.

#### 35 U.S.C. § 101

The Examiner has rejected claims 110-117 and 120-126 under 35 U.S.C. § 101 for lack of patentable utility.

The claims are drawn to methods for manufacturing a microarray that has single exon probes that share at least one customer-identified attribute. Because applicants do not understand the Examiner to mean that methods of manufacturing demonstrably useful products – nucleic acid microarrays – lack utility, applicants believe that the rejection is not addressed to the invention as presently claimed, and thus respectfully request that it be withdrawn.

35 U.S.C. § 112, ¶ 1 Enablement

The Examiner has rejected claims 110-117 and 120-126 under 35 U.S.C. § 112 ¶ 1 for lack of enablement, based on the corresponding rejection of these claims under 35 U.S.C. § 101 for lack of utility.<sup>2</sup> Because the § 101 rejection is in error for the reasons advanced above, applicants respectfully request that the rejection for lack of enablement be withdrawn.

35 U.S.C. § 112, ¶ 1 Written Description

The Examiner has rejected claims 110-117 and 120-126 under 35 U.S.C. § 112, 1 for lack of written description. The Examiner argues that the specification provides insufficient written description to support the genus encompassed by at

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<sup>2</sup> The Examiner quotes from the background section of the disclosure that "identification of functional genes from genomic data remains, however, an imperfect art" and argues that one skilled in the art would not know how to predictably use the claimed invention without undue experimentation. As applicants noted with respect to the § 101 rejection, this argument does not appear to be addressed to the invention as presently claimed.

least claims 125 and 126 and that, except for the elected species (SEQ ID NO:17240), the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides.

The pending claims are drawn to methods of manufacturing a microarray. The claims require, among other things, that "at least 50% of the probes addressably disposed on said microarray are single exon probes that include a fragment ... selectively hybridizable at high stringency to an expressed gene". In claim 125, as amended, each of the addressably disposed probes must comprise "a nucleotide sequence selected from the group consisting of exon SEQ ID NO:s set forth in Tables 4, 5, 6, 7, 8, 9, 10, 11, 12, and 13 and the complete complements thereof", and further that each of the probes "hybridizes under high stringency conditions to a nucleic acid molecule expressed in human cells or tissues".

Applicants submit that the specification of the instant application sufficiently describes the claimed invention. As noted recently by the Federal Circuit, "the written description requirement can be met by 'show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ... i.e., complete or partial structure, other physical and/or chemical properties, *functional characteristics when coupled with a known or disclosed correlation between function and structure*, or some combination of such characteristics.'" *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1324 (Fed. Cir. 2002) (quoting *Guidelines for Examination of Patent Applications*

*Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, 66 Fed. Reg. 1099 (Jan. 5, 2001)).*

Complete structures are provided in the instant specification for all of the nucleotide sequences set forth in Tables 4 - 13, and one of skill in the art could readily determine structures for "the complete complements thereof". Moreover, the specification provides on p. 78 an explicit definition of the term "high stringency conditions" for purposes of solution phase and microarray-based hybridizations. Example 9 of the training materials accompanying the PTO's Revised Interim Written Description Guidelines describes a situation in which the claim language required high stringency hybridization. According to the analysis for that example, "a person of skill in the art would not expect substantial variation among species encompassed within the scope of the claims because the highly stringent hybridization conditions set forth in the claim yield structurally similar DNAs. Thus, a representative number of species is disclosed, since highly stringent hybridization conditions in combination with the coding function of DNA and the level of skill and knowledge in the art are adequate to determine that applicant was in possession of the claimed invention."

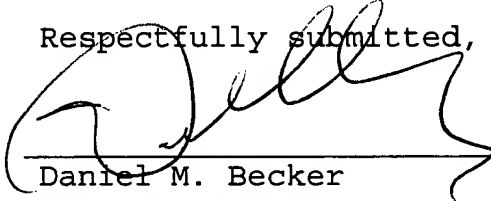
Applicants submit that, as was the case in Example 9 of the training materials, the instant specification provides disclosure adequate to support the claimed invention. They therefore respectfully request withdrawal of the rejection for lack of written description.

CONCLUSION

Applicants respectfully submit that claims 110 - 117 and 120 - 126, all of the claims now pending, are free of rejection or objection. Applicants thus respectfully submit that the claims are in good and proper form for allowance, and respectfully request the same.

If the Examiner believes that any issues remain outstanding, Applicants respectfully request that the Examiner call the undersigned for a telephonic interview.

Respectfully submitted,



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Enclosures

- 1) Copy of Declaration for instant application, filed on May 23, 2001.
- 2) Copy of Application Data Sheet for instant application, filed on May 23, 2001.
- 3) Copy of Filing Receipt for priority document, US 60/207456, filed on May 26, 2000.
- 4) Copies of acknowledgement postcards, date-stamped by the PTO November 30, 2001, August 23, 2002, and October 4,



2002, confirming the filing and receipt of Information Disclosure Statements with cited documents for the instant application.

5) CD-R containing an electronic copy of priority document, US 60/207456, as filed on May 26, 2000.